

06. CHEMICALS MANAGEMENT

OVERVIEW

The legislative framework created by the adoption of the Law on Chemicals¹³³ and the Law on Biocidal Products¹³⁴ and the relevant bylaws has established a modern chemicals management system, which is significantly harmonized with EU regulations. **It is necessary to continue with the further development of the legislative framework, through further harmonization of regulations, taking into account new EU regulations, as well as amendments to existing ones, and strengthen the capacities necessary for the implementation of regulations.**

The **Draft Law on Biocidal Products** for the purpose of harmonization with the Biocidal Products Regulation – BPR (528/2012/EU) was completed in 2018. The **Law is expected to be adopted in 2019.**

In 2018, the **Draft Law on Consumer Goods** was adopted, and is currently in parliamentary procedure.

Regarding the administrative capacities for performing professional activities in this area there were no significant changes in relation to the capacities in the previous period.

In 2018, a pilot version of the e-platform for the entry of chemicals into the Integrated Register of Chemicals (eIRH) was established and a period of testing was conducted, and **in January 2019 this electronic platform started its work.**

With regard to Persistent Organic Pollutants (POPs), since the updated National Implementation Plan (NIP) for the implementation of the Stockholm Convention on POPs by the Government of the Republic of Serbia has not yet been adopted, (although it was prepared in 2015) it is now becoming outdated, and it is difficult to implement activities from specific action plans that are an integral part of the updated NIP.

The system of financing the management of chemicals and biocidal products is not in compliance with the basic principles established within EU regulations. **In this sense, the Draft Law on Biocidal Products, which is expected to be enforced in 2019, did not take over the system of fees according to the EU model because it is not in accordance with the domestic system that regulates collection of taxes and fees, which needs to be amended as soon as possible.**

LEGISLATIVE FRAMEWORK

The legislative framework created by the adoption of the Law on Chemicals and the Law on Biocidal Products and the relevant bylaws established a modern chemical management system based on EU principles. The Law on Chemicals is in line with

133 "Official Gazette of the Republic of Serbia", No.36/2009, 88/2010, 93/2012 and 25/2015

134 "Official Gazette of the Republic of Serbia", No. 36/2009, 88/2010, 92/2011 and 25/2015

with the REACH Regulation (EC 1907/2006)¹³⁵ to a large extent with the exception of the provisions for which the implementation of the EU membership is necessary, such as registration and authorization procedures. **It is necessary to continue with the further development of the legislative framework, through further harmonization of regulations, taking into account new EU regulations, as well as amendments to the existing ones, and strengthening the capacities necessary for the implementation of regulations.**

Regarding the updating of regulations related to the classification and labeling of chemicals in order to adapt them in terms of technical and scientific progress, there were no changes in relation to the last report. Domestic legislation is aligned with the EU to the seventh ATP¹³⁶. **However, further harmonization needs to be continued, given that these regulations are additionally updated in the EU (ATP 8, 9, 10, 11, 12 and 13), of which the application of ATPs 8, 9 and 10 become binding in the EU in 2018. We emphasize that regular harmonization of these regulations is of great importance, since the delay in updating the List of Classified Substances has as an effect on the data on harmonized substances in Serbia that deviate from those in the EU.** Therefore, in some cases, there is a deviation in the implementation of the prescribed provisions on the classification and labeling of the same substances and mixtures when they are found on the EU and RS market. This is contrary to the basic GHS goal which states that chemicals should be classified and labeled according to the same rules and in the same way in all markets. This discrepancy may result in difficulties in the free traffic of chemicals from the imports, as well as the protection of human health and the environment.

In order to update the regulations governing **restrictions and prohibitions of production, and placing on the market and use of chemicals**, in April 2018, amendments were adopted¹³⁷ that we consider extremely important, and they relate, among other things, to bisphenol A (BPA), decabromodiphenylether (decaBDE) and perfluorooctanoic acid (PFOA). **In this way, EU Regulation 2016/2235 from December 2016, which prohibits/restricts the use of BPA in thermal paper at a concentration greater than or equal to 0.02%, was transposed with the beginning of its application in Serbia as of June the 30th, 2020 (six months later in relation to the EU).** In addition, the manufacturing or marketing of products containing decaBDE at a concentration equal to or greater than 0.1% (m/m) after the 2nd of March 2022 is prohibited.

In March 2018, amendments were made to the List of Candidate Substances for the List of Substances of Very High Concern¹³⁸ **thereby enabling consumers to obtain information on a number of substances of very high concern (SVHCs) in products, including bisphenol A and perfluorohexane-1- sulfonic acid.** However, further harmonization needs to be done as the list was additionally updated in the EU in June 2018 and January 2019 by the addition of 16 new substances.

135 <http://www.ekologija.gov.rs/organizacija/sektori/sektor-za-upravljanje-zivotnom-sredinom/odeljenje-za-hemikalije/reach/?lang=lat>

136 Adaptation to technical progress (ATP)

137 "Official Gazette of the Republic of Serbia", No. 36/2018

138 "Official Gazette of the Republic of Serbia", No. 22/2018

The List of Substances of very high Concern was also supplemented in March 2018¹³⁹ resulting in full compliance with the EU List (43 substances are now on that list), an action which was also planned by the latest NPAA¹⁴⁰.

In May 2018, amendments were made to the Rulebook on permits for performing business activities and/or permits for the use of particularly hazardous chemicals¹⁴¹, which **annulled the previous provision that chemicals classified in the category of danger of corrosive damage/skin irritation of the subcategory 1B are considered particularly hazardous chemicals**. This was also a remark that was explained in detail in the previous report, since the introduction of this measure in 2017 was not based on the really dangerous aspect that subcategory 1b represents and was not applicable in practice both from the aspect of the type of product to which it was applied, and the aspect of the economic entities covered by it.

There is a significant delay in the process of the harmonization of regulations relating to methods of testing hazardous properties of chemicals that have not been updated since 2012.

The drafting of the Draft Law on Biocidal Products for the purpose of harmonization with the Biocidal Products Regulation (528/2012/EU) commenced in 2017 and was completed in 2018. The public hearing was held between October the 25th and November the 23rd, 2018. The EU Regulation could not be fully taken into account, since it regulates, among other things, the procedures that are conducted by the European Chemicals Agency (ECHA) or the European Commission; thereby ensuring the maximum possible compliance with the EU Regulation until full EU membership. **However, the new law will not bring about substantial changes in relation to the current one, and the only significant change concerns new biocidal products that have been approved by the European Commission or the competent authority of a member state in the EU in the sense that they will not be able to be registered in the Temporary List, but they will have to conduct the recognition procedure.** This should facilitate the operation of importers of biocidal products from the EU, since they already have access to their necessary documentation, but given that a new procedure is being introduced by state authorities with limited administrative and professional capacity in these jobs, this will certainly represent a new challenge. The enforcement of the new law is planned for the second quarter of 2019 on the basis of the NPAA.

In 2018, the **Draft Law on Consumer Goods** was adopted, which is currently undergoing Parliament procedure. Objects of general use in accordance with this Law include: toys, cosmetics, detergents and biocidal products. We emphasize that the term "general purpose goods" is not recognized in the EU regulations, but it is taken from the SFRY regulations. Public debate on this law was held between July the 13th and August the 3rd, 2018 in the course of which ALHem took active participation and sent comments, suggestions and proposals to the Ministry of Health in writing.

139 *ibid*

140 National Program for the Adoption of the EU Acquis (NPAA) Third Revision, February 2018, Ministry of European Integration

141 "Official Gazette of the Republic of Serbia", No. 6 since January 27, 2017; 29 since April 13, 2018.

ALHem's general remark on this draft law is that it is based on an outdated concept of health and safety, not only in terms of terminology and legal-technical issues, but more significantly in the non-compliance of the system. The EU concept is based on the general, integrated safety of products, which is primarily regulated by the general product safety directive, and certain groups of products are further regulated by special conditions that regulate the special conditions for their placing on the market - chemicals, toys, cosmetics, biocides, plant protection products, etc.

In that sense, our basic remark related to the intention of the legislator to "bring back" detergents and biocidal products to this law as "hygiene products". The placement of detergents and biocidal products on the market is completely regulated by the Law on Chemicals and the Law on Biocidal Products, or by the accompanying bylaws. There is no rational nor well-founded argument for the Ministry of Health's allegations that the established system does not "cover" health and safety. The entire concept of the Law on Chemicals and the Law on Biocidal Products is to put safe products on the market - safe from the standpoint of their toxicological, ecotoxicological and physical-chemical properties. Pursuant to this Law, the competent authority for placing a biocidal product on the market shall evaluate the biocidal product for all intended uses. This assessment includes a hazard assessment based on data on physical and chemical, toxicological and ecotoxicological properties of the active substance and biocidal product, the assessment of exposure of humans, animals and the environment in all exposure scenarios, and the assessment of the efficacy of the biocidal product. The goal is to place only those products that do not represent an unacceptable risk to life and health of people and the environment on the market. In addition to the EU regulations transposed into these two laws, the EU regulates further placing of detergents and biocidal products on the market.

It is clear that for such a concept there are certain interest groups, primarily the Public Health Institutes in Serbia, which issue health certificates, and which is contrary to the principle of supplier's responsibility for the product being placed on the market, as well as the principle of market control. All this leads to problems in the implementation of regulations related to these product groups, in particular biocidal products for which the supplier, prior to placing the product on the market, should be granted a permit, i.e. "decision on the entry of a biocidal product into the Temporary List of Biocidal Products" by the competent authority (Ministry of Environmental Protection). In practice, it might happen that an approved biocidal product for some reason does not "pass" a health and safety check and thus cause a standstill in the movement of goods, but more importantly, it can also mislead consumers about the safety of this product. It is not clear to us which additional parameters are further controlled within the health and safety of the biocidal product (laboratory testing) that have not already been considered in the approval procedure for placing the biocidal product on the market.

ALHem also had a remark about the very objectives of the enforcement of this law, since it was our opinion environmental protection was omitted as an important aspect of managing general purpose goods (at the end of its life cycle, these products become waste, which can be recycled into new products or end up at the landfill). This is also the only ALHem remark that has been passed.

Considering that the Draft of this law has already been passed by the Government of the Republic of Serbia (despite several negative opinions, including the opinion of the Ministry of Environmental Protection in charge of chemicals and biocidal products management), and that it is in the phase of parliamentary adoption, we expect that the competent bodies of the EU will have objections regarding these mismatches and will react in a timely manner.

Regarding the administrative capacities for performing professional activities in this area there were no significant changes in relation to the capacities in the previous period. Although the last Rulebook on the systematisation of jobs of the competent ministry foresees a significant increase in the number of employees working in chemicals and biocidal products management, it must be taken into account that the limitation of the number of employees in state authorities was extended in 2019, so it is not realistic to expect it will create opportunities for significant strengthening of administrative and professional capacities within the Ministry of Environmental Protection; although this is necessary in order to reach the staffing levels necessary for the implementation of regulations, as well as for the development of a further chemicals management system.

It is important to note that the project “Mercury Initial Assessment in the Republic of Serbia” was completed in 2018 and it is the basis for ensuring and developing the necessary capacities for the implementation of the Regulation on Mercury (2017/852). In 2018, the realization of the project “Strengthening Synergies between the Basel, Rotterdam, Stockholm and Minamata Conventions in Republic of Serbia” started in cooperation with UNDP funding from the special trust fund of UNEP. The project aims to strengthen the synergy of international agreements in the field of chemicals management and waste management, as well as coordination of reporting obligations under international agreements.

IMPLEMENTATION OF LEGISLATION

The Department for Chemicals at the Ministry of Environmental Protection is in charge of **affairs related to implementation of administrative procedures** in this area. The prescribed administrative procedures are being implemented, but given the scope and content of the documentation required by these procedures, as well as the confidentiality of certain data, it is necessary to improve the implementation of these procedures through **development of a modern electronic data delivery system** with adequate protection and strictly defined levels of access to data. This need has been identified within the Draft of the National Programme of Environmental Protection (NPEP) for the period from 2015 to 2019 as a measure to improve the procedure for the entry of chemicals into the Chemicals Register, but the same approach should be applied in the case of administrative procedures in relation to biocidal products.

In 2018, a pilot version of the e-platform for entry of chemicals into the Integrated Register of Chemicals (eIRH)¹⁴² was established and a period of testing was conducted. Thus, this electronic **platform started to work from January 2019**, which means

142 <https://irhportal.ekologija.gov.rs/Account/Login>

that the data needed for the entry of chemicals that were calculated in 2018 in the Register of Chemicals can be delivered via e-platform. The introduction of this possibility to business entities will be a simplified and cheaper administrative procedure. It is also expected that the verification of the submitted data and the issuance of a certificate by the competent authority will be accelerated. However the administrative procedure from the moment of submission of data up to the final decision on the issuance of the chemical entry into the registry breaks the deadlines prescribed by all the laws and lasts for several years on average (especially for those businesses that register a large number of chemicals). Strengthening the administrative capacity which will perform the registration of chemicals is more than necessary. The decisions for requests from previous years for which no solutions have yet been found must be issued quickly by simplifying procedures in terms of requests for additional documentation, since a large number of these chemicals are no longer in circulation; or their classification, labeling, and very often composition has changed. **The actual effects of the application of the electronic platform can be expected in the coming period**, but certainly the initial data entry for chemicals to which no registration number has been assigned thus far, requires significant engagement.

In addition, further development of the **Biocidal Product Register within the Integrated Register of Chemicals is needed**.

In the course of 2019, the implementation of the project **“Further development of the framework for harmonization with EU legislation in the field of Air, Chemicals and Horizontal Legislation” (EAS 3 project)** will begin, during which, specific implementation plans for the REACH Regulation and the Law on Biocidal Products will be developed.

As far as POPs chemicals are concerned, the activities from specific action plans that represent an integral part of the updated NIP are difficult to implement since the updated National Implementation Plan (NIP) for the implementation of the Stockholm Convention by the Government of the Republic of Serbia has not been passed yet and it is becoming outdated. In particular, the implementation of POPs monitoring based on the established activities of the program for measuring the level of POPs in the environment and food, as well as the inclusion of new POPs in the existing program are also proving difficult to maintain. In order to establish a functional POPs monitoring system, it is necessary to improve the work at laboratories for measuring, especially new POPs, through the accreditation of methods, procurement of laboratory equipment and training of laboratory personnel.

Over the course of 2018, the international network IPEN, Arnika, HEAL and 17 other European organizations, including the Association of “Safer Chemicals Alternative” from Serbia, conducted a survey¹⁴³ **showing that consumer products including children’s toys from recycled plastics, were contaminated with toxic chemicals, so-called “burning retarders” that can be found in electronic waste and are forbidden, i.e. restricted for use on the basis of adverse effects on human health and the**

143 Toxic loophole recycling hazardous waste into new products, Arnika, IPEN, HEAL et al. 2018 <http://www.alhem.rs/wp-content/uploads/2018/10/toxic-loophole-recycling-hazardous-waste-into-new-products.pdf>

environment. These are toxic chemicals that are known to affect fertility, fetal development, the thyroid gland and can cause neurological problems and attention disturbances in children. Electronic waste contains bromine compounds that are used as burning retarders in electronic equipment to slow down the rate of fire propagation or fire intensity. The compounds include polybrominated diphenyl ethers (PBDEs) such as OctaBDE¹⁴⁴ and DecaBDE¹⁴⁵, as well as HBCD¹⁴⁶ listed in the Stockholm Convention on POPs. A study analyzing 109 toys and hair accessories indicated that 107 samples (98%) were contaminated with measurable polybrominated diphenylether (PBDE) concentrations and 55 samples (41%) contained hexabromocyclododecane (HBCD). Of the 5 products made from black hard plastic purchased on the Serbian market (four toys and one hairclip) and tested in a laboratory, two samples exceeded the permitted 1000 ppm of decaBDE, while three products exceeded the permitted 10 ppm of octaBDE for products from the original (non-recycled) plastics, but not the allowed concentration for recycled plastic products, which is the case here.

The prescribed permissible concentration for octaBDE in non-recycled plastic products is 10 ppm, while for recycled plastic products 1000 ppm is allowed, which is worrying, since the endocrine system of children “does not differentiate” whether the toy is made of new or recycled plastic when exposed to PBDE. **Unequal standards for PBDE content in products made from original (non-recycled) and recycled plastics are the result of prescribed high limit values for POPs waste as well as recycling exemptions given to some of the signatory parties to the Stockholm Convention at their request, including the EU.** This “toxic” loophole in the regulations means that despite the increased concentration of PBDE in the tested samples, most of the products do not exceed the legally permitted limit because they are made of recycled materials.

These regulatory inequalities are motivated by recycling targets that have neglected the effects of contamination of new products during recycling; thus continuing the process of exposure to these substances. Although recycling targets in the EU are globalized through international conventions, hazardous electronic and electrical waste finds its way across state borders and it gets recycled again through recycling workshops. This toxic loophole, hidden from the public, poses a threat to the health of children, consumers, employees in recycling workshops and the local population, as well as all other vulnerable groups in society. **The only way to protect people from hazardous chemicals from recycled waste is to close the toxic loopholes and keep such hazardous waste away from recycling flows.** The report of this survey contains recommendations addressed to the competent institutions in the EU.

Since the regulations on chemicals only relate to one phase of the chemicals’ life cycle, i.e. to placing on the market and use of chemicals, and bearing in mind the fact that there are other phases of chemicals life-cycle (from production to disposal), it is very important to achieve cooperation and coordination of the department responsible for the implementation of regulations on chemicals with other relevant sectors;

144 Commercial octabromodiphenyl ether (OctaBDE) is listed on the Stockholm Convention List as hexabromodiphenyl and heptabromodiphenyl ether.

145 Dekabromodiphenyl ether (DecaBDE) is listed as a commercial mixture of DecaBDE.

146 HBCD is hexabromocyclododecane.

primarily in the field of environmental protection. This cooperation and co-ordination is necessary in view of the need for the synchronized undertaking of activities that are within the competence of different sectors in order to ensure adequate management of chemicals through the entire life cycle and implementation of the principles of the Strategic Approach to International Chemicals Management (SAICM)¹⁴⁷. **To date, there is no information on the establishment and operation of the Joint Body, nor the adoption of the Integrated Chemicals Management Program, which is envisaged by the Law on Chemicals (Article 7).** We expect that the results of the project “Strengthening the synergies between the Basel, Rotterdam, Stockholm and Minamata Conventions at the national level in the Republic of Serbia “ will contribute to better coordinations of work in the field of chemicals and waste management, as well as reporting to the obligations under these international agreements.

FINANCING

Considering that the financial aspect of chemicals management and biocidal products has been thoroughly analyzed in previous reports¹⁴⁸, it is important to take into account the fact that no changes have been introduced since then. The system of chemicals management and biocidal products is financed from the budget of the Republic of Serbia. **Due to the structure and functioning of the budget system, the data on the amount of revenue generated from the fees which are used to cover the costs of providing administrative services for the implementation of administrative procedures is not available. It is not known whether, and to what extent, is the cost paid from the funds generated from other taxpayers, or those who do not generate income from chemicals and/or biocidal products.** This is not in line with the basic principles set out in REACH and the Biocidal Products Regulations (BPR), as well as the accompanying EU Regulations governing fees (Regulation (EC) No. 340/2008 and Regulation (EU) No. 564/2013), according to which **the costs related to regulatory procedures in respect of chemicals and biocidal products must be borne by economic operators who, from placing them on the market, earn income.** In this sense, the new law on biocidal products, which is expected to be enforced in 2019, did not take over the system of fees according to the EU model as it is not in accordance with the domestic system that regulates collection of taxes and fees, which needs to be amended as soon as possible. Given that the appropriated funds (fees), among other things, would be used to assess the hazards, exposures and risks of bottled products (which is not part of the usual administrative procedure), all citizens of Serbia would benefit because human health and the environment is being protected in this way.

147 Strategic Approach to International Chemicals Management - SAICM

148 Coalition 27 (2017): Chapter 27 in Serbia: Still Under Construction; Coalition 27 (2018): Chapter 27 in Serbia: No - progress Report

RECOMMENDATIONS

Legislative framework:

- Establish adequate dynamics of harmonization with relevant amendments to EU regulations in this field.
- Adopt the Draft Law on Biocidal Products.

Implementation of Legislation:

- It is necessary to strengthen administrative and professional capacities in this area, especially in the field of entering chemicals into the Register and managing biocidal products, especially due to the introduction of the new procedure for the recognition of the EU act which arises from the Draft Law on Biocidal Products.
- Further development of the Register for Biocidal Products within the Integrated Register of Chemicals is needed.
- Review the requirements for the entry of chemicals into the Register of Chemicals from the previous years for which no decisions have yet been issued by way of procedure simplification in terms of requests for supplementary documentation.
- The Government of Republic of Serbia needs to adopt an updated NIP for the implementation of the Stockholm Convention on POPs before holding the ninth Conference of the signatory parties to the Stockholm Convention in 2019.
- Establish a Joint Body for the purpose of planning, monitoring, harmonizing and undertaking joint measures of various inspections in charge of control and supervision of chemicals and biocidal products.
- Establish a Joint Body for integrated chemical management in order to establish satisfactory cooperation and coordination between all relevant sectors and ensure safe chemicals management throughout its life cycle, i.e. the adoption and implementation of the Integrated Chemicals Management Program. The joint body should consist of representatives of competent state authorities in the field of chemicals management, industry, scientific-research organizations and non-governmental organizations.

Financing:

- Modify the domestic system governing the collection of fees and charges in terms of taking over the EU model of financing chemicals and biocidal products management systems to ensure that the fees related to regulatory procedures in respect of chemicals and biocidal products are born by economic operators who generate income by placing the same on the market.